SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Vaniprevir Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Specific target organ toxicity - repeated exposure (Oral): Category 2 (gallbladder, Liver)
Short-term (acute) aquatic hazard: Category 3

GHS label elements
Hazard pictograms: 

Signal Word: Warning

Hazard Statements: H373 May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.
H402 Harmful to aquatic life.

Precautionary Statements: Prevention:
P260 Do not breathe dust.
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention if you feel unwell.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerides, C8-10</td>
<td>85409-09-2</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Vaniprevir</td>
<td>923590-37-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Polyethylene glycol castor oil</td>
<td>61791-12-6</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a
### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions**

- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**

- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

**Technical measures**

- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

**Local/Total ventilation**

- Use only with adequate ventilation.

**Advice on safe handling**

- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure.
### Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

### Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaniprevir</td>
<td>923590-37-8</td>
<td>TWA</td>
<td>300 µg/m³</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### Engineering measures:
- Ensure adequate ventilation, especially in confined areas.
- Minimize workplace exposure concentrations.
- Apply measures to prevent dust explosions.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

### Personal protective equipment

#### Respiratory protection
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Combined particulates and organic vapor type

#### Hand protection
- **Material**: Chemical-resistant gloves

#### Eye protection
- **Remarks**: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

- **Eye protection**: Wear the following personal protective equipment:
  - Safety goggles

#### Skin and body protection
- **Remarks**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

- **Skin and body protection**: Skin should be washed after contact.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: powder
- **Color**: tan
- **Odor**: odorless
- **Odor Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Density**: 1 g/cm³
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Glycerides, C8-10:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute inhalation toxicity : LD50 (Rat): > 1.86 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Vaniprevir:
Acute oral toxicity : LD50 (Rat): > 750 mg/kg
Remarks: No adverse effect has been observed in acute toxicity tests.
LD0 (Dog): > 300 mg/kg  
Remarks: No adverse effect has been observed in acute toxicity tests.

LD50 (Mouse): > 2.000 mg/kg  
Remarks: No mortality observed at this dose.

**Polyethylene glycol castor oil:**

- **Acute oral toxicity**
  - LD50 (Rat): > 5.000 mg/kg

- **Acute dermal toxicity**
  - LD50 (Rat): > 2.000 mg/kg  
    - Method: OECD Test Guideline 402  
    - Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Glycerides, C8-10:**

- **Species:** Rabbit  
- **Method:** OECD Test Guideline 404  
- **Result:** No skin irritation  
- **Remarks:** Based on data from similar materials

**Vaniprevir:**

- **Species:** Rabbit  
- **Result:** No skin irritation

**Polyethylene glycol castor oil:**

- **Species:** Rabbit  
- **Method:** OECD Test Guideline 404  
- **Result:** No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Glycerides, C8-10:**

- **Species:** Rabbit  
- **Result:** No eye irritation  
- **Method:** OECD Test Guideline 405  
- **Remarks:** Based on data from similar materials

**Vaniprevir:**

- **Species:** Bovine cornea  
- **Result:** Mild eye irritation  
- **Method:** Bovine cornea (BCOP)
Polyethylene glycol castor oil:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Glycerides, C8-10:
Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Vaniprevir:
Test Type : Local lymph node assay (LLNA)
Species : Mouse
Result : negative

Polyethylene glycol castor oil:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Glycerides, C8-10:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
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Result: negative
Remarks: Based on data from similar materials

Vaniprevir:
Genotoxicity in vitro: Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Polyethylene glycol castor oil:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative

Carcinogenicity
Not classified based on available information.

Components:
Vaniprevir:
Species: Rat, male and female
Application Route: Oral
Activity duration: 104 Weeks
Result: >= 120 mg/kg body weight

Species: Mouse
Application Route: Oral
Activity duration: 6 Months
Result: >= 300 mg/kg body weight
Target Organs: gallbladder

Reproductive toxicity
Not classified based on available information.

Components:
Glycerides, C8-10:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
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Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Vaniprevir:

Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
General Toxicity Parent: NOAEL: \( \geq 250 \) mg/kg body weight
Result: No effects on fertility.

Effects on fetal development:
Test Type: Development
Species: Rat, female
Application Route: Oral
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Developmental Toxicity: LOAEC F1: 180 mg/kg body weight
Symptoms: No specific developmental abnormalities.
Result: negative

Test Type: Development
Species: Rabbit, female
Application Route: Oral
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Developmental Toxicity: NOAEL F1: \( \geq 240 \) mg/kg body weight
Symptoms: No specific developmental abnormalities.
Result: negative

Polyethylene glycol castor oil:

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.
Components:

Vaniprevir:

Routes of exposure : Ingestion
Target Organs : gallbladder, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Glycerides, C8-10:

Species : Rat
NOAEL : >= 1.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 407
Remarks : Based on data from similar materials

Vaniprevir:

Species : Rat
NOAEL : 120 mg/kg
LOAEL : 360 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Liver

Species : Dog
NOAEL : 15 mg/kg
LOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 9 Months
Target Organs : Liver, gallbladder
Symptoms : Gastrointestinal disturbance

Species : Mouse
NOAEL : 150 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : Liver, Kidney, Gastrointestinal tract, Heart, gallbladder, Stomach

Polyethylene glycol castor oil:

Species : Rat
NOAEL : > 5.000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.
Experience with human exposure

Components:

Vaniprevir:
Ingestion: Symptoms: stomach discomfort, Diarrhea, Nausea, Headache

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycerides, C8-10:
Toxicity to fish: LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: NOEC (Desmodesmus subspicatus (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Vaniprevir:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 4 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.
LC50 (Americamysis): > 4 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms: EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Polyethylene glycol castor oil:**

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 45 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: LC50 (Mysisidopsis bahia (opossum shrimp)): > 50 mg/l
Exposure time: 48 h

Toxicity to microorganisms: EC50: 2,8 mg/l
Exposure time: 5 min

**Persistence and degradability**

**Components:**

**Glycerides, C8-10:**
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

**Vaniprevir:**
Biodegradability: Result: not rapidly degradable
Method: OECD Test Guideline 314

**Polyethylene glycol castor oil:**
Biodegradability: Result: rapidly degradable
Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Glycerides, C8-10:**
Partition coefficient: n-octanol/water: log Pow: < 4

**Vaniprevir:**
### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues**: Dispose of in accordance with local regulations.
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

- **UNRTDG**: Not regulated as a dangerous good
- **IATA-DGR**: Not regulated as a dangerous good
- **IMDG-Code**: Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

### SECTION 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Argentina. Carcinogenic Substances and Agents Registry**: Not applicable
- **Control of precursors and essential chemicals for the preparation of drugs**: Not applicable

**International Regulations**

**The ingredients of this product are reported in the following inventories:**

- **AICS**: not determined
- **DSL**: not determined
SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SATD - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guideline for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
## SAFETY DATA SHEET

**Vaniprevir Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

AR / Z8